



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0369]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations
Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements of FDA's regulations implementing the Federal Import Milk Act (FIMA).

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Domini Bean,
Office of Information Management,
Food and Drug Administration,
1350 Piccard Dr.,
PI50-400T,
Rockville, MD 20850,
301-796-5733,
[domini.beam@fda.hhs.gov](mailto:domini.bean@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper

performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Regulations Under the Federal Import Milk Act--21 CFR Part 1210 (OMB Control Number
0910-0212)--Extension

Under FIMA (21 U.S.C. 141-149), milk or cream may be imported into the United States only by the holder of a valid import milk permit (21 U.S.C. 141). Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50° F (21 U.S.C. 142).

FDA's regulations in part 1210 (21 CFR part 1210) implement the provisions of FIMA. Sections 1210.11 and 1210.14 require reports on the sanitary conditions of, respectively, dairy farms and plants producing milk and/or cream to be shipped to the United States. Section 1210.12 requires reports on the physical examination of herds, while § 1210.13 requires the reporting of tuberculin testing of the herds. In addition, the regulations in part 1210 require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number,

and shipper's name and address (§ 1210.22). Section 1210.20 requires that an application for a permit to ship or transport milk or cream into the United States be made by the actual shipper.

Section 1210.23 allows permits to be granted based on certificates from accredited officials.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1210.11	FDA 1996/Sanitary inspection of dairy farms	2	200	400	1.5	600
1210.12	FDA 1995/Physical examination of cows	1	1	1	0.5	0.5
1210.13	FDA 1994/Tuberculin test	1	1	1	0.5	0.5
1210.14	FDA 1997/Sanitary inspections of plants	2	1	2	2	4
1210.20	FDA 1993/Application for permit	2	1	2	0.5	1
1210.23	FDA 1815/Permits granted on certificates	2	1	2	0.5	1
Total						607

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden¹

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1210.15	2	1	2	0.05	0.10

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated number of respondents and hours per response are based on FDA's experience with the import milk permit program and the average number of import milk permit holders over the past 3 years. FDA estimates that two respondents will submit approximately 200 Form FDA 1996 reports annually, for a total of 600 responses. FDA estimates the reporting burden to be 1.5 hours per response, for a total burden of 607 hours.

The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. To date, Form FDA 1815 has been submitted in lieu of these forms. Because FDA has not received any Forms FDA 1994 and 1995 in the last 3 years, the Agency estimates no more than one will be submitted annually. FDA estimates the reporting burden for each to be 0.5 hours per response for a total burden reporting burden of 0.5 hours each.

FDA estimates that two respondents will submit one Form FDA 1997 report annually, for a total of two responses. FDA estimates the reporting burden to be 2.0 hours per response, for a total burden of 4 hours. FDA estimates that two respondents will submit one Form FDA 1993 report annually, for a total of two responses. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 1 hour. FDA estimates that two respondents will submit one Form FDA 1815 report annually, for a total of two responses. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 1 hour.

With regard to records maintenance, FDA estimates that approximately two recordkeepers will spend 0.05 hours annually maintaining the additional pasteurization records required by § 1210.15, for a total of 0.10 hours annually.

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2)), the time, effort, and

financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of business activities.

Dated: April 16, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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